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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,158	01/04/2002	Jan Weber	12013/59401	1766

23838 7590 10/03/2003

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EXAMINER

STEWART, ALVIN J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 10/03/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No. 10/035,158	Applicant(s) WEBER ET AL.	
	Examiner Alvin J Stewart	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Groups I and II in Paper No. 7 is acknowledged.

Claims 19-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Claim Objections

Claims 12 and 17 are objected to because of the following informalities: claims 12 and 17 are the same claims. Cancellation of one of the claims is required. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 11, 13-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillstead US Patent 5,116,318 in view of Sahatjian et al US Patent 5,843,089.

Hillstead discloses a system comprising: an expandable stent (32), a compliant sheath (40) and an expandable balloon (34). The stent is in contact and crimped over the sheath (see Fig. 4) and the sheath is made of Latex (see col. 4, lines 36-37). The sheath comprises a tube (see Fig. 2) and the tube comprises a length that is greater than the length of the stent (see Fig.

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3). Finally, the tube is attached to the balloon at the proximal and distal ends (see Fig. 9 and col. 5, lines 43-45).

Regarding claim 7, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the end of the compliant sheath of the Hillstead reference because Applicant has not disclosed that by closing about at least one of a distal end of the sheath provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the two ends of the sheath open (as discloses by the Applicant in paragraph 27) because the sheath will greatly reduces, if not completely obviates, the winging effect frequently observed in different balloon catheters (see col. 4, lines 64-68 and col. 5, lines 1-4).

Therefore, it would have been an obvious matter of design choice to modify Hillstead reference to obtain the invention as specified in claim 7.

Regarding claim 18, the Hillstead reference discloses a tube made of Latex, therefore, the material is capable of being translucent. It has been held that a claim is anticipated if each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice. *Kalman vs. Kimberly-Clark Corp.*, 218 USPQ 789.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillstead US Patent 5,116,318 in view of Sahatjian et al US Patent 5,843,089 as applied to claim 1 above, and further in view of Hyde et al EP 0553960A1.

Hillstead as modify by Sahatjian discloses a sheath fixedly attached to the balloon at the proximal and distal ends of the balloon. However, Hillstead as modify by Sahatjian do not disclose an adhesive located between the sheath and the balloon.

Hyde et al discloses a balloon connected to the rest of the catheter by an adhesive for the purpose of sealingly connects the two structures together.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fixation method of the Hillstead reference with the adhesive of the Hyde et al reference in order to sealingly connects the two structures together.

Claims 12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillstead US Patent 5,116,318 in view of Sahatjian et al US Patent 5,843,089 as applied to claim 1 above, and further in view of Savin et al US Patent 4,950,227.

Hillstead as modify by Sahatjian discloses the invention substantially as claimed. However, Hillstead as modify by Sahatjian do not disclose a lubricant for the purpose of reducing the fiction between structures.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Hillstead reference with the lubricant solution of the Savin et al reference in order to reduce the fiction between structures.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 703-305-0277. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

A handwritten signature in black ink, appearing to read 'Alvin Stewart', with a stylized flourish at the end.

Alvin Stewart
September 24, 2003.